

REMARKS/ARGUMENTS

Applicants acknowledge receipt of the Final Office Action dated March 23, 2007. Claims 1-10 and 23 are pending in the application. Claims 1, 7, and 23 have been amended. New claims 26-27 have been added. No new matter was added with the amendments or the new claims.

In the Response, the Examiner maintained the objection to the Specification and priority. In addition, the Examiner rejected claims 1-3, 6, 8, and 9 under 35 U.S.C. § 102(a) as being anticipated by Cubbage et al., Eighth Annual Orthopedic Resident Research Forum, vol. 8, 2002 ("*Cubbage*"). Moreover, the Examiner rejected claims 1-6, 9-10, and 23 under 35 U.S.C. § 103(a) as being unpatentable over *Cubbage* in view of Lei et al., U.S. Patent No. 6,777,445 ("*Lei*"). The Examiner also rejected claims 1-8 and 23 under 35 U.S.C. § 103(a) as being unpatentable over Unger et al., U.S. Patent No. 6,123,923 ("*Unger*") in view of Monforte et al., U.S. Patent No. 6,635,452 ("*Monforte*"). Applicants believe all pending claims are allowable over the art of record and respectfully request reconsideration and allowance of all claims.

I. Priority

The Examiner has denied Applicants' claim of priority of claims 1-10 and 23 to U.S. Provisional Application 60/356,856, filed February 14, 2002 ("the '856 Provisional") and maintains that the priority date of claims 1-9 is that of U.S. Provisional Application No. 60/446406, filed February 11, 2003. The Examiner's objection and denial of priority has been rendered moot in light of the reasoning below. As will be shown, *Cubbage* cannot be considered prior art for the purposes of 35 USC § 102(a). Thus, no further arguments are necessary to address the priority date issue. However, Applicants note that this is not an admission that Applicants are not entitled to the claim of priority. To the contrary, Applicants maintain the assertion that priority is properly claimed to the '856 Provisional and disagree with the Examiner's denial of priority.

II. Claims 1-3, 6, 8, and 9 are not anticipated by Cubbage.

The Examiner has rejected claims 1-3, 6, 8, and 9 under § 102(a) as being anticipated by *Cubbage*. According to the Manual of Patent Examining Procedure (MPEP), "Applicant's disclosure of his or her own work within the year before the [priority date] *cannot* be used against him or her under 35 U.S.C. 102(a)." MPEP § 2132.01 (citing In re Katz, 687 F.2d 450,

215 USPQ 14 (CCPA 1982)) (Emphasis added). Applicants respectfully note to the Examiner that the authors of *Cubbage* are also the inventors of the pending application. As such, Applicants assert that *Cubbage* cannot be considered prior art for the purpose of § 102(a) in view of MPEP § 2132.01. Nevertheless, in further support of this assertion, Applicants submit an affidavit under 37 CFR 1.132 stating that *Cubbage* is describing Applicants' own work. Consequently, *Cubbage* cannot anticipate claims 1-3, 6, 8, and 9 because it cannot be considered prior art under 35 U.S.C. § 102(a) and respectfully request withdrawal of the rejection.

III. Claims 1-6, 9-10, and 23 are patentable over *Cubbage* in view of *Lei*.

The Examiner has rejected claims 1-6, 9-10, and 23 under 35 U.S.C. § 103(a) as being unpatentable over *Cubbage* in view of *Lei*. Applicants traverse. As discussed above, *Cubbage* cannot be considered prior art for the purposes 35 U.S.C. § 103(a) as *Cubbage* is a publication describing the Applicants' own work. Because *Cubbage* is unavailable as prior art, Applicants submit that claims 1-6, 9-10, and 23 are patentable over *Cubbage* and *Lei*, and respectfully request that the Examiner withdraw the § 103 rejections thereof.

IV. Claims 1-8 and 23 are patentable over *Unger* in view of *Monforte*.

The Examiner has rejected claims 1-8 and 23 under 35 U.S.C. § 103(a) as being unpatentable over *Unger* in view of *Monforte*. Applicants traverse. In order to establish a *prima facie* case of obviousness, the Examiner must meet the following three elements: 1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings; 2) there must be a reasonable expectation of success; and 3) the prior art reference(s) must teach or suggest all the claim limitations. MPEP § 2143 (2005) (citing *In re Vaack*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)). If just one of these elements is not met, the Examiner has failed to establish a case of obviousness. Applicants respectfully submit that the Examiner has failed to make a *prima facie* case of obviousness in rejecting claims 1-8 and 23.

Applicants submit that no motivation or suggestion exists to combine *Unger* and *Monforte*. According to the MPEP, "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so." MPEP § 2143.01 (citing *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006)). "The mere fact that references can be combined

or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” *Id.* (citing *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)).

Applicants first note that neither reference, by itself, teaches or suggests “a targeting agent coupled to a fullerene moiety; and one or more antibiotic molecules coupled to the fullerene moiety” as recited in amended claims 1 and 23. *Monforte* is directed to a mass label tag attached to *a* single reactive group. *Monforte*, col. 23, lns. 1-60; Figure 1. The reactive group is used to secure the mass label to a molecule of interest for mass spectrometry. Specifically, *Monforte* is interested in attaching a mass label to a specific gene sequence for analysis. *Monforte*, Examples 1-7. In other words, *Monforte* desires a very specific interaction with the mass label/reactive group to a target molecule (i.e. DNA). Attaching two different types of reactive groups would destroy the specificity *Monforte* desires as the mass label would be targeted to two different types of molecules. Moreover, nothing in *Monforte* suggests the use or desirability of compounds for therapeutic use. Thus, *Monforte* does not teach or suggest both a targeting agent coupled to a fullerene moiety; and one or more antibiotic molecules coupled to the fullerene moiety nor would one of ordinary skill in the art be motivated to modify *Monforte* to produce the combination recited in claims 1 and 23.

On the other hand, *Unger* is directed to encapsulating photoactive agents with vesicles or hollow carriers, where the vesicles may be attached to a targeting moiety. *Unger*, Figures 1-7; col. 2, lns. 1-29. The only potential teaching of *Unger* regarding a targeting moiety and a fullerene is an antibody-bound photoactive agent to provoke an immune response. *Unger*, col. 13, lns. 60-65. With respect to targeting ligands, *Unger* only teaches covalent linking of targeting ligands to the stabilizing material and *not* the photoactive agent itself. *Unger*, col. 55. Furthermore, *Unger* does not contemplate coupling one or more antibiotics a fullerene moiety. Accordingly, *Unger* does not teach or suggest the combination of limitations of claims 1 and 23.

In view of the above teachings, one of ordinary skill in the art would not be motivated to combine *Monforte* and *Unger* to produce the invention of claims 1 and 23. Both of these references are directed to targeted **tagging** of molecules or tissue for analysis, either through mass spectrometry or imaging. As mentioned above, *Monforte* teaches reactive groups, such as antibiotics, as biomolecules capable of specific recognition. *Monforte*, col. 23, lns. 48-49. That

is, *Monforte* does not contemplate therapeutic use of antibiotics or other bioactive agents. *Unger* does teach use of bioactive agents such as antibiotics for therapeutic use. However, since *Monforte* is only directed to mass label screening and already teaches reactive groups such as antibodies, enzymes, etc, there would be no reason or motivation to modify *Monforte* with *Unger*, especially when *Monforte* does not even contemplate therapeutic applications. Conversely, one of ordinary skill in the art would not be motivated to modify *Unger* with *Monforte*, as *Unger* already teaches use of reactive groups (*i.e.* targeting ligands) with a photoactive agent.

Furthermore, Applicants stress that it would not be apparent to one skilled in the art to couple one or more antibiotics and a targeting agent to a fullerene moiety from the cited references, when the words “fullerene” and “antibiotics” are buried in a long list of possible compounds, especially when neither reference contains any teaching on whether such a combination would be successful or how such a combination could be accomplished. In light of the above reasoning, it is clear that the references do not suggest the desirability of the invention recited in claims 1 and 23 and therefore, a *prima facie* case of obviousness has not been made.

Applicants further assert that, contrary to MPEP § 2143.02, a reasonable expectation of success has not been shown with respect to combining or modifying the prior art references. Applicants emphasize that *Monforte* and *Unger* only peripherally disclose fullerenes and antibiotics. Neither *Monforte* nor *Unger* provide any guidance as to how one of ordinary skill in the art would couple a fullerene to an antibiotic. Nanotechnology and pharmaceuticals are highly unpredictable and complex arts. See MPEP 2164.03. Nothing in either *Monforte* or *Unger* suggests whether a fullerene-antibiotic conjugate comprising a targeting agent coupled to a fullerene moiety; and one or more antibiotic molecules coupled to the fullerene moiety could successfully be synthesized. Significantly, *Monforte* and *Unger* provide no examples or data showing success with a targeting agent coupled to a fullerene moiety; and one or more antibiotic molecules coupled to the fullerene moiety. At best, this is an “obvious to try” situation, which is the improper standard. If the Examiner is relying on her own knowledge, Applicants respectfully request the Examiner submit an affidavit in accordance with 37 CFR 1.104(d)(2).

Applicants therefore submit that the Examiner has not established a *prima facie* case of obviousness in rejecting claim claims 1 and 23, because, contrary to MPEP § 2143, the Examiner

has failed to cite references that teach or suggest all of the elements recited in the rejected claims. In addition, since independent claim 1 is submitted to be allowable, dependent claims 2-8 must *a fortiori* also be allowable, as they carry with them all the limitations of claim 1. Accordingly, Applicants respectfully request that the Examiner withdraw the § 103 rejections of claims 1-8 and 23.

V. New claims 26-27 are patentable over Unger in view of Monforte

New claims 26-27 are dependent on independent claims 1 and 23, respectively. Claims 26-27 both recite “wherein said fullerene-antibiotic conjugate is water-soluble.” Nothing in *Unger* teaches or suggests wherein said fullerene-antibiotic conjugate is water-soluble. *Unger* teaches, nearly in passing, that fullerenes may be used as a photoactive agent. *Unger*, col. 12, line 40. Nowhere does *Unger* explicitly disclose a fullerene-antibiotic conjugate, let alone wherein said fullerene-antibiotic conjugate is water-soluble. Fullerenes are known to be hydrophobic and thus, wherein said fullerene-antibiotic conjugate is water-soluble cannot be considered an inherent property of a fullerene-antibiotic conjugate. See N. Tagmatarchis and M. Prato, Carbon-based materials: From fullerene nanostructures to functionalized carbon nanotubes, 77 Pure Appl. Chem. 1675 (2005). As *Unger* completely lacks any teaching regarding fullerene chemistry and methods, it cannot possibly teach or suggest wherein said fullerene-antibiotic conjugate is water-soluble. As such, *Unger* does not teach or suggest the claim limitations.

Unger in combination with *Monforte* also does not teach or suggest all the claim limitations. *Monforte* is directed to attaching a mass label to a reactive group for characterization of a target molecule. Nowhere does *Monforte* teach wherein said fullerene-antibiotic conjugate is water-soluble. Like *Unger*, *Monforte* only mentions fullerenes in passing as one of many possible compounds for use as a mass label. *Monforte* says nothing regarding fullerene properties or chemistry and clearly does not teach wherein said fullerene-antibiotic conjugate is water-soluble. Thus, *Unger* in combination with *Monforte* does not teach or suggest all the claim limitations.

Applicants, thus submit that new claims 26-27 are patentable over *Unger* in view of *Monforte* because, contrary to MPEP § 2143, the references do not teach all the limitations of the claims. As such, Applicants respectfully request allowance of new claims 26-27.

VI. Conclusion

Applicants respectfully request reconsideration, allowance of the claims, as amended, and a timely Notice of Allowance be issued in this case. If the Examiner feels that a telephone conference would expedite the resolution of this case, the Examiner is respectfully requested to contact the undersigned.

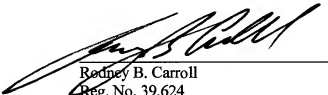
In the course of the foregoing discussions, Applicants may have at times referred to claim limitations in shorthand fashion, or may have focused on a particular claim element. This discussion should not be interpreted to mean that the other limitations can be ignored or dismissed. The claims must be viewed as a whole, and each limitation of the claims must be considered when determining the patentability of the claims. Moreover, it should be understood that there may be other distinctions between the claims and the prior art that have yet to be raised, but which may be raised in the future.

If any fees are inadvertently omitted or if any additional fees are required or have been overpaid, please appropriately charge or credit those fees to Conley Rose, P.C. Deposit Account Number 50-1515.

Respectfully submitted,

Date: _____

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